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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,473	09/29/2004	Buchi Reddy Reguri	BULK 3.3-003	8343

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EXAMINER	
COLEMAN, BRENDA LIBBY	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/509,473	REGURI ET AL.	
	Examiner	Art Unit	
	Brenda L. Coleman	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-11,13 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,2 and 4-9* is/are allowed.

6)☒ Claim(s) *10,11,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 2, 4-11, 13 and 14 are pending in the application.

This action is in response to applicants' amendment filed February 3, 2006. Claims 1, 2, 4, 5, 7-11, 13 and 14 have been amended and claims 3, 12 and 15 have been canceled.

Response to Amendment

Applicant's amendments filed February 3, 2006 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 10-15 of the last office action labeled paragraph 2, the applicant's arguments have been fully considered, however they were not found persuasive. Claims 10-15 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for schizophrenia, does not reasonably provide enablement for all disorders claimed herein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The scope of the method claims are not adequately enabled solely based on olanzapines inhibitory effect on disorders of the central nervous system provided in the specification.

In evaluating the enablement question, several factors are to be considered. In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988); Ex parte Forman, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or

absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

The nature of the instant invention has claims, which are crystalline polymorph Form-BI of Olanzapine.

HOW TO USE: Claims 13 and 14 are to a method of treating a disorder of the central nervous system. Any evidence presented must be commensurate in scope with the claims and must clearly demonstrate the effectiveness of the claimed compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims of the instant invention call for the treatment of any and all diseases associated with the central nervous system.

Where the utility is unusual or difficult to treat or speculative, the examiner has authority to require evidence that tests relied upon are reasonably predictive of in vivo efficacy by those skilled in the art. See *In re Ruskin*, 148 USPQ 221; *Ex parte Jovanovics*, 211 USPQ 907; MPEP 2164.05(a).

Patent Protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute enabling disclosure. *Genentech Inc. v. Novo Nordisk* 42 USPQ2d 1001.

Claims 10, 11, 13 and 14 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for schizophrenia, does not reasonably provide enablement for all disorders claimed herein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected,

to make and/or use the invention commensurate in scope with these claims, for reasons of record and stated above.

2. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 3) of the last office action, which are hereby **withdrawn**.

3. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 101 rejection of claim 15, labeled paragraph 4) of the last office action, which is hereby **withdrawn**.

4. With regards to the 35 U.S.C. § 102(b), anticipation rejection of claims 1, 8 and 10-15, labeled paragraph 5 of the last office action. The applicants' amendments with respect to claims 1 and 8, which were limited to the crystalline polymorph Form-VI is found persuasive and herein withdrawn. However, with regards to claims 10, 11, 13 and 14, the applicants' arguments have been fully considered, however they were not found persuasive. As stated by the applicants "polymorphs arise when molecules of a compound arrange in the solid state in distinct ways". "By varying the temperature of the solution and using different solvents, different polymorphs can be formed." "Although identical in chemical composition, polymorphs can have very different properties." "Polymorphs are distinguishable by various analytical techniques, especially X-ray powder diffraction patterns." It is the solid crystalline form of olanzapine that possesses the crystalline polymorph Form-VI characteristics. Thus the pharmaceutical composition must contain a solid form of the crystalline polymorph Form-VI olanzapine in the pharmaceutical

composition in order that the characteristics of the polymorph be retained. However, the applicants are not specifically claiming solid pharmaceutical compositions, but a composition comprising crystalline Form-VI olanzapine and a pharmaceutically acceptable carrier, diluent, excipient, additive, filler, lubricant, binder, stabilizer, solvent or solvate. The specification on page 8 discusses for example a solution in the preparation of the pharmaceutical compositions of the instant invention, which would no longer possess the crystalline olanzapine. Claims 10, 11, 13 and 14 fails to specifically claim a solid pharmaceutical composition.

Claims 10, 11, 13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by BEASLEY et al., U.S. Patent No. 6,159,963, for reasons of record and stated above.

5. With regards to the 35 U.S.C. § 102(b), anticipation rejection of claims 1 and 8-15, labeled paragraph 6 of the last office action. The applicants' amendments with respect to claims 1, 8 and 9, which were limited to the crystalline polymorph Form-VI is found persuasive and herein withdrawn. However, with regards to claims 10, 11, 13 and 14, the applicants' arguments have been fully considered, however they were not found persuasive. As stated by the applicants "polymorphs arise when molecules of a compound arrange in the solid state in distinct ways". "By varying the temperature of the solution and using different solvents, different polymorphs can be formed." "Although identical in chemical composition, polymorphs can have very different properties." "Polymorphs are distinguishable by various analytical techniques, especially X-ray powder diffraction patterns." It is the solid crystalline form of olanzapine that possesses the crystalline polymorph Form-VI characteristics. Thus the pharmaceutical composition must contain a

solid form of the crystalline polymorph Form-VI olanzapine in the pharmaceutical composition in order that the characteristics of the polymorph be retained. However, the applicants are not specifically claiming solid pharmaceutical compositions, but a composition comprising crystalline Form-VI olanzapine and a pharmaceutically acceptable carrier, diluent, excipient, additive, filler, lubricant, binder, stabilizer, solvent or solvate. The specification on page 8 discusses for example a solution in the preparation of the pharmaceutical compositions of the instant invention, which would no longer possess the crystalline olanzapine. Claims 10, 11, 13 and 14 fails to specifically claim a solid pharmaceutical composition.

Claims 1 and 8-15 are rejected under 35 U.S.C. 102(b) as being anticipated by BEASLEY et al., U.S. Patent No. 5,776,928, for reasons of record and stated above.

6. With regards to the 35 U.S.C. § 102(b), anticipation rejection of claims 1 and 10-15, labeled paragraph 7 of the last office action. The applicants' amendments with respect to claim 1, which was limited to the crystalline polymorph Form-VI is found persuasive and herein withdrawn. However, with regards to claims 10, 11, 13 and 14, the applicants' arguments have been fully considered, however they were not found persuasive. As stated by the applicants "polymorphs arise when molecules of a compound arrange in the solid state in distinct ways". "By varying the temperature of the solution and using different solvents, different polymorphs can be formed." "Although identical in chemical composition, polymorphs can have very different properties." "Polymorphs are distinguishable by various analytical techniques, especially X-ray powder diffraction patterns." It is the solid crystalline form of olanzapine that possesses the crystalline

polymorph Form-VI characteristics. Thus the pharmaceutical composition must contain a solid form of the crystalline polymorph Form-VI olanzapine in the pharmaceutical composition in order that the characteristics of the polymorph be retained. However, the applicants are not specifically claiming solid pharmaceutical compositions, but a composition comprising crystalline Form-VI olanzapine and a pharmaceutically acceptable carrier, diluent, excipient, additive, filler, lubricant, binder, stabilizer, solvent or solvate. The specification on page 8 discusses for example a solution in the preparation of the pharmaceutical compositions of the instant invention, which would no longer possess the crystalline olanzapine. Claims 10, 11, 13 and 14 fails to specifically claim a solid pharmaceutical composition.

Claims 1 and 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by BUNNELL et al., U.S. Patent No. 5,631,250, for reasons of record and stated above.

7. With regards to the 35 U.S.C. § 102(b), anticipation rejection of claims 10-12, labeled paragraph 8 of the last office action, the applicants' arguments have been fully considered, however they were not found persuasive. As stated by the applicants "polymorphs arise when molecules of a compound arrange in the solid state in distinct ways". "By varying the temperature of the solution and using different solvents, different polymorphs can be formed." "Although identical in chemical composition, polymorphs can have very different properties." "Polymorphs are distinguishable by various analytical techniques, especially X-ray powder diffraction patterns." It is the solid crystalline form of olanzapine that possesses the crystalline polymorph Form-VI characteristics. Thus the pharmaceutical composition must contain a solid form of the crystalline polymorph Form-VI

olanzapine in the pharmaceutical composition in order that the characteristics of the polymorph be retained. However, the applicants are not specifically claiming solid pharmaceutical compositions, but a composition comprising crystalline Form-VI olanzapine and a pharmaceutically acceptable carrier, diluent, excipient, additive, filler, lubricant, binder, stabilizer, solvent or solvate. The specification on page 8 discusses for example a solution in the preparation of the pharmaceutical compositions of the instant invention, which would no longer possess the crystalline olanzapine. Claims 10, 11, 13 and 14 fails to specifically claim a solid pharmaceutical composition.

Claims 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by CHAKRABARTI et al., U.S. Patent No. 5,229,382, for reasons of record and stated above.

In view of the amendment dated February 3, 2006, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

a) Claim 14 is a substantial duplicate of claim 10, as the only difference is a statement of intended use, which is not given material weight. Note In re Tuominen 213 USPQ 89.

Allowable Subject Matter

9. Claims 1, 2 and 4-9 are allowed. None of the prior art of record nor a search in the pertinent art area teaches the crystalline polymorph Form-VI and the process of preparing the crystalline polymorph Form-VI of 2-methyl-4-(4-methyl-1-piperazine)-10H-thieno[2,3-b][1,5]benzodiazepine as claimed herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brenda Coleman

Brenda L. Coleman
Primary Examiner Art Unit 1624
April 16, 2006